OIPE JC102 NOV 2 1 2002 PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

BONNET, et al. Atty. Dck. No. 024118-00012

Application Number: 09/423,858 Art Unit: 3732

Filed: February 25, 2002 Examiner: Lewis, Ralph A.

For: PREFORM FOR OBTAINING AFTER DEFORMATION CUSTOMISED ORTHODONTIC APPLIANCES OR DENTAL ORTHOPAEDICS RESULTING APPLIANCES AND METHODS FOR OBTAINING SAME

DECLARATION OF FRANCOIS BONNET UNDER 37 CFR 1.132

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I, Francois Bonnet, declare as follows:

1. I am one of the inventors of the above-identified application and am fully familiar with the subject matter thereof, as well as the references relied upon by the Examiner.

2. I understand that the claims in the above-identified application are considered by the Patent Office to be unpatentable over the Nilsson reference (U.S. Patent No. 4,391,861). I have read and understood the Office Action dated May 21, 2002, the pending application, and the Nilsson reference.

3. As described in the pending application, the process for producing a Nighttime Lingual Envelope ("NLE") was entirely manual prior to the invention of the subject matter of the present application. The manual method of producing NLE's was expensive in both time in preparation and in cost given the difficulties in properly positioning the tongue while preparing the NLE.

4. The specification of US Patent Application No. 09/423,858 unambiguously discloses a preform, which after deformation, allows for (1) the production of personalized orthodontic or dento-facial orthopedic apparatuses, (2) the process of manufacturing said personalized apparatus, (3) an expansion core suited to said process and (4) the apparatus directly obtained by said process. The claimed preform presents the general form of a three-dimensional hollow body which allows the preform's expansion inside a mold, thereby reproducing the morphology of a subject. Moreover, the preform has a shape which is as close as possible to the final form desired after deformation. The claimed preform excludes preforms that present both a constant thickness of the walls and also having a shape presenting a revolution axis.

5. It is submitted that the use of a preform to manufacture "custom-sized" orthodontic apparatuses is a novel concept.

First, the claimed invention yields a final apparatus starting from a plastic material preform. This preform has been designed so that it undergoes a minimum of deformation to reach a typical patient morphology, thereby increasing liability, solidity and reproducibility. In other words, one of the main advantages of the present invention is the provision of preforms which possess external surfaces that are as close as possible to the final external surface of the orthodontic apparatus. The present invention, therefore, permits better control over the structure of the final apparatus, unlike the Nilsson reference.

Additionally, as it is well known in the art, the amount of deformation of the apparatus structure directly correlates to the thinning or other changes of the apparatus wall thickness the during the process. Hence, the present invention's advantage of

reduced deformation is of great benefit. Additionally, the present invention allows one to easily obtain (and in one attempt) a custom sized (i.e., adapted to each individual patient) apparatuses by using one of relatively few preforms (i.e., preforms of different sizes).

Furthermore, it is an essential feature the shape of the claimed preform (generally itself obtained in series by hot molding injection which is a very low cost process) do not present a revolution axis. Indeed, a preform that present a revolution axis (i.e., such as that disclosed in Nilsson) would be far from the final form of the orthodontic apparatuses (whose shape is the internal mouth of the patient modified by the rules of the art of orthodontics) and then result in a final apparatus that is far removed from the presently claimed requirement of the orthodontic apparatuses. In Figures 1 and 2 of the present specification, an example (for NLE) of such a preform and the final apparatus are presented, and it can be seen that the external surface of the preform is close to that of the final apparatus, and that neither the preform nor the final apparatus present a revolution axis. Figures 3 and 4 also show the final apparatus produced. Therefore, the present invention is distinguishable from that of Nilsson because the present invention do not present a revolution axis and on the contrary the preform (initial shape before process) is close (and smaller) to the internal human mouth shape (modified by the rules of the art of orthdontics), that is the shape desired for the apparatus (final shape after process).

Second, the claimed invention has the advantage of obtaining a predetermined thickness of the apparatus wall (after the expansion phase) in predetermined locations. As known in the art, a prime requisite in the manufacture of orthodontic apparatuses is the control exerted over the final shape. However, this control must not only extend to the external surface, but also to the thickness of the walls. The thickness of the walls is important in order to permit the patient the full range of normal functions (i.e., swallowing, breathing, relative movements of the jaws) and also for comfort. Therefore, the first goal in carrying out this objective is to leave available the maximum amount of space possible for the tongue. For this goal to be successful, the general thickness of the walls must be

as thin as possible (typically 0.8 to 1.5 mm). However, it is more advantageous for there to be a greater thickness (typically 2.5 to 4 mm) in certain and precise local areas to either transmit strains with neither deformation nor failure, or to allow the inserting of attachments or hooks (generally made of metal). One of the main advantages of the claimed invention is that it provides preforms in which the local thickness is variable and controlled, unlike Nilsson.

It is, therefore, a key point of distinction between the cited art and the present invention that the present invention provides a preform in which the expansion is controlled so as to produce a final apparatus which possesses predetermined variable thicknesses in predetermined locations. In Figure 2 of the specification, an example of an NLE can be seen in which the local thickness of the preform is variable. Figures 3 and 4 also show the final apparatus with a variable thickness. Therefore, the present invention differs from Nilsson in this respect as well.

6. It is submitted that the Nilsson patent discloses a preform of thermoplastic material composed of a number of separate part-preforms fitted into one another in readiness for blow molding to form a finished container. The part-preforms are singly or jointly provided with barrier layers. These barrier layers are intended to only allow the passage of gases or light to a very slight extent (cf. col. 1, line 29-30). It is submitted that the Nilsson preform is not adapted to undergo an expansion phase to yield an orthodontic apparatus, unlike the present invention. Additionally, as stated previously, the Nilsson's preform presents a revolution axis and has a constant thickness. This submission is based on the following reasons.

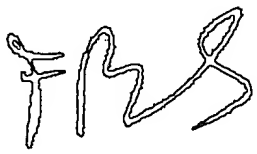
The "expansion" phase of the present invention is a key phase of the claimed process. During the blow molding of a preform, i.e., during the expansion phase, the reduction of initial thickness in a point of the wall depends on two variables. The first is the quantity of local strain, which is determined by the general strain of the area (the "distance to run" during molding). The second variable is preform thickness which is

determined by the local curvature radius of the targeted internal surface of the mold. The wall's thickness will increase proportionally to the shortness of the distance and the length of the radius of the preform (s e Figure 5, points of type C and D). If the preform as proposed by Nilsson presents constant thickness and revolution axis (as shown on the figure 5 attached), the final local thickness is variable only as a result of the above described phenomena and influenced neither by the operator, nor by the designer, unlike the present invention which permits for areas of the preform to be pre-selected by the designer for variable thicknesses. The only parameter for the Nilsson product designer to consider is the initial thickness. Therefore, local extra-thickness necessary for transmitting strains and inserting attachments will not be obtained following Nilsson, and the molded form will be unsuitable for use without many and heavy reinforcements (for example, the adding of resin) by another process. Therefore, the present invention is distinguishable from the Nilsson patent for these reasons as well.

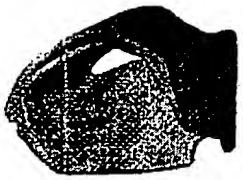
7. The undersigned declarant declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001, of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this 20th day of November, 2002.

Francois Bonnet



ELN OR D



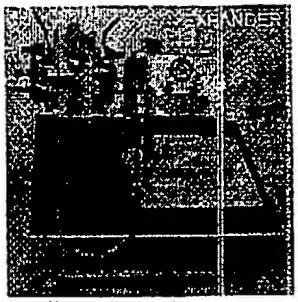
ELN ORTHO DEVELOPPEMENT

Development of Dento Facial Orthopedics products

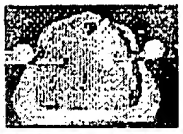
The NLE of Bonnet is 15 years old. Its ever-increasing use by practitioners made it the number one of the lingual repositioning apparatuses.

Nevertheless it remains difficult, even hazardous, to be manufactured and to be repeated again during the treatment.
In order to allow space for the tongue and to leave the bone structure free, it must be thin and precisely adapted to each patient.

ELN MULTIEXPAN ®,
new process to manufacture the Night time Lingual Envelope makes NLE proceed to the semi-industrial stage



General shape and thickness guaranteed by the use of preforms



More transparency, toughness in use, neatness, brought by the qualities of the material

Fast personalization of the preform by hot expansion on EXPANDER, using inflated nut and plaster models of the patient (in 10 to 15 mn)

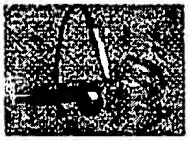
Conformity to the prescription given by the expansion control device

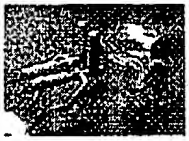
Toughness to alternate stresses, less breakages during treatment, due to the high pressure hot molding of preforms

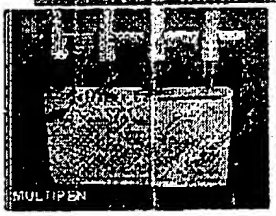
Possible adaptations by usual manual processes: machining, gluing, resin addition

Keeping of the plaster models as study models

QUALITY LIABILITY CONFORMITY
ADAPTABILIT RAPIDITY CLEANLINESS







The Korn, Sahar (palatine points for expansion) or others types of hooks are hot inserted in workshop. MULTIPEN allows also to finish the NLE and to tune the hooks position with no noise or dust near the patient before placing it in mouth and for adaptations during the treatment.(hot cutting off, dragging or replacing of hooks)

Prototype pictures
No contractual document

ELN OR D company was created in December 1998 to:

Develop and propose to the professionals (Technicians, Orthodontists,) in attractive technical and economical conditions the means (equipments, products, trainings and assistance) to realize the apparatuses useful to "growing therapies"

French Patent FR 0706082
International W 09951472
CE Certification in course
Development program supported by ANVAR
(Agence Nationale de la Valorisation de la Recherche)
(French Valorization of Research Agency

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François BONNET

Annex to the DECLARATION UNDER RULE 132 by Mr François BONNET

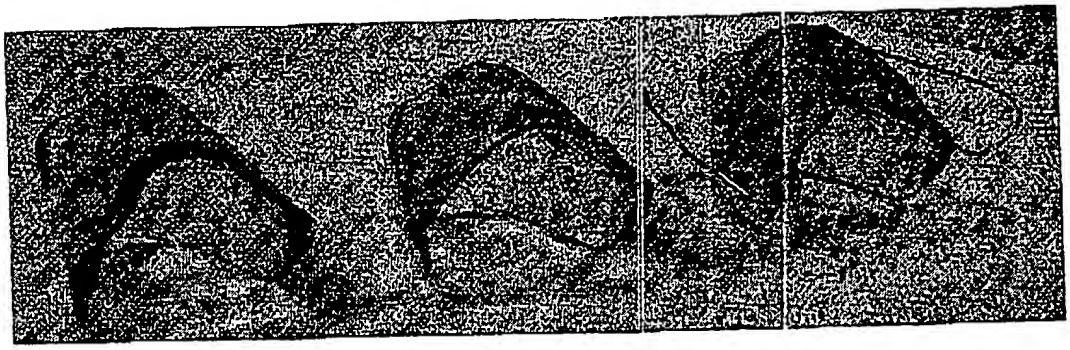

Figure 1: rear view of, from left to right,

preform expanded preform finished apparatus with hooks

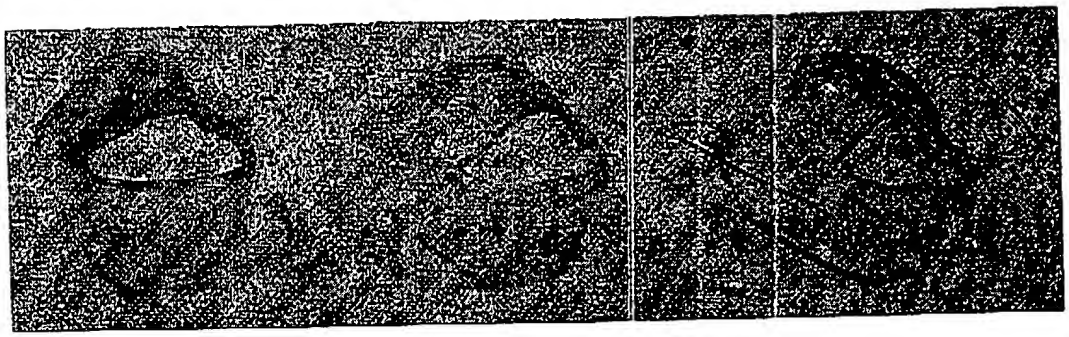

Figure 2: front view of, from left to right,

preform expanded preform finished apparatus with hooks

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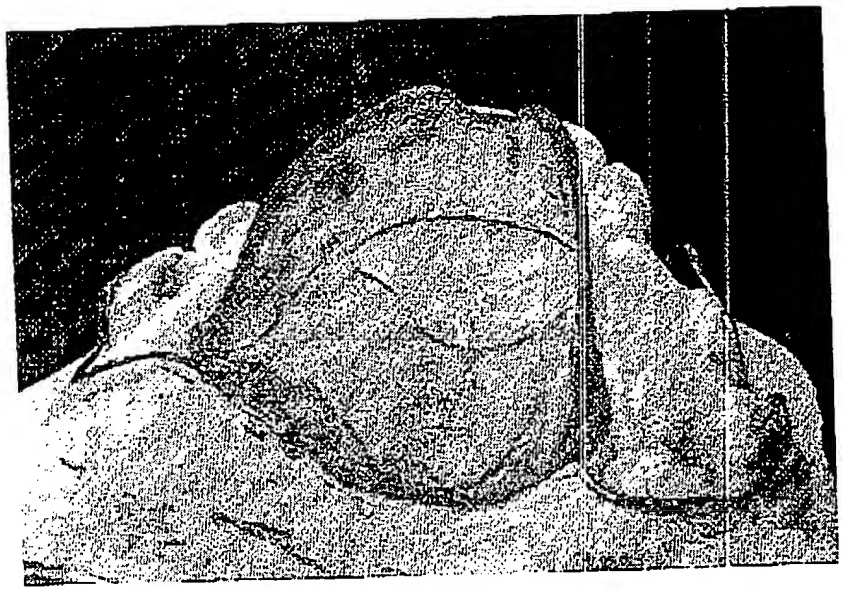

Figure 3

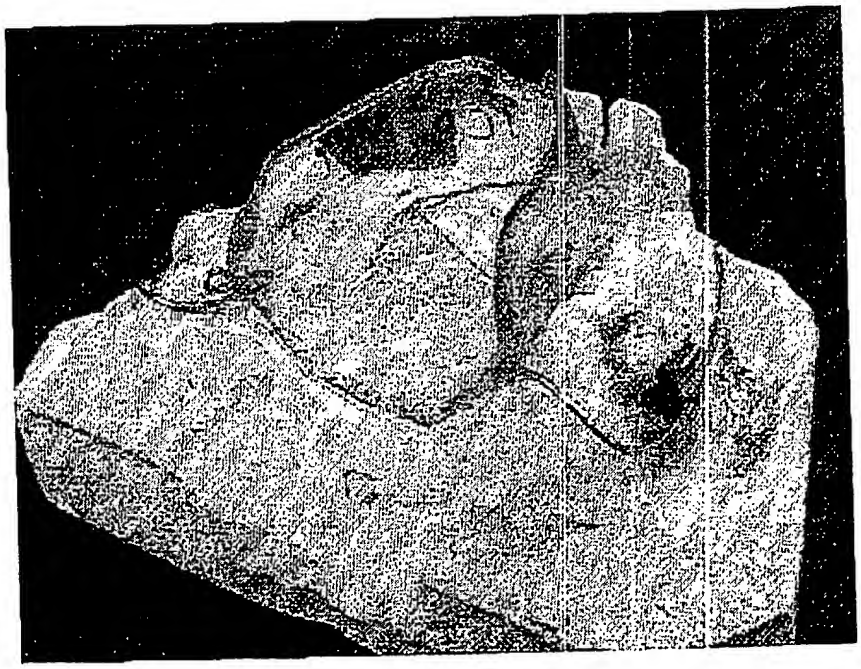

Figure 4

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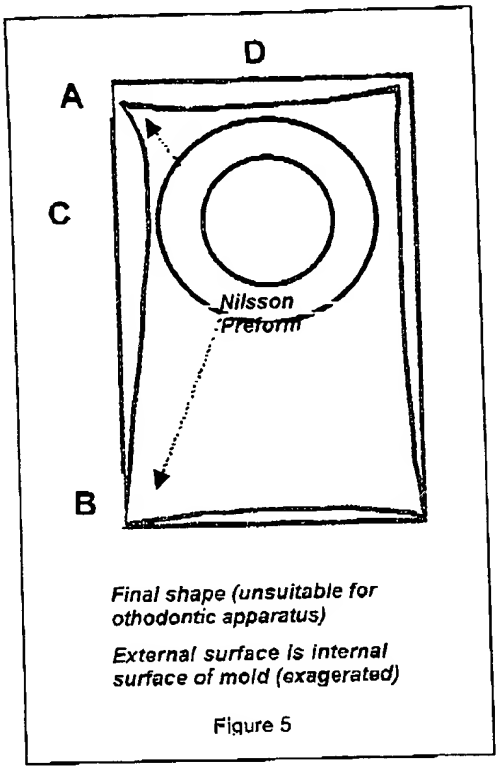
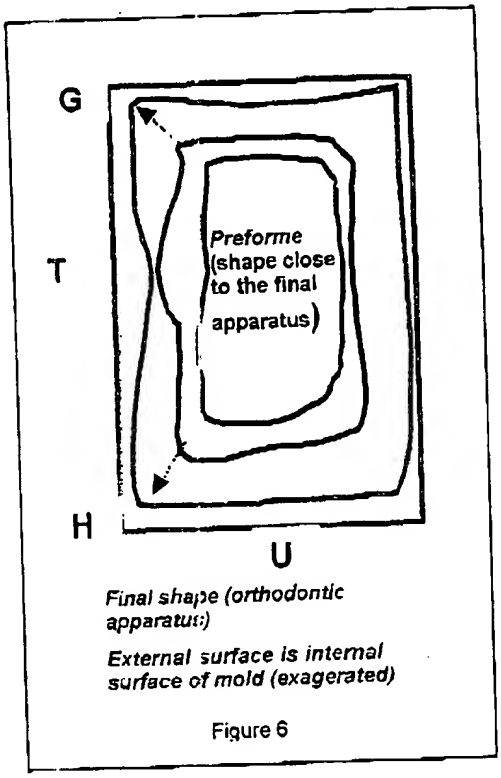


Final shape (unsuitable for othodontic apparatus)

External surface is internal surface of mold (exagerated)

Figure 5



Final shape (orthodontic apparatus)

External surface is internal surface of mold (exagerated)

Figure 6

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17 pages (s)